

FormType: Category

Title: QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS

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An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 The process, site, facility, and/or environmental system to be tested shall be described.
- 1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

- 2.1 Key points of contact for each organization involved in the project shall be identified.
- 2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.
- 2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

- 3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

- 3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.
- 3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.
- 3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.
- 3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.
- 3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

- 4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.
- 4.2 Known site-specific factors that may affect sampling/monitoring procedures shall be described.
- 4.3 Any site preparation needed prior to sampling/monitoring shall be described.
- 4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.
- 4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).
- 4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final

concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

- 4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.
- 4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.
- 4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.
- 4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.
- 4.11 Describe how samples are uniquely identified.
- 4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.
- 4.13 Holding time requirements shall be noted.
- 4.14 Procedures for packing and shipping samples shall be described.
- 4.15 Procedures to maintain chain_of_custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.
- 4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

- 5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA_approved or similarly validated methods shall be specified.
- 5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.
- 5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

- 6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.
- 6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.
- 6.3 The specific procedures used to assess all identified QA objectives shall be fully described.
- 6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.
- 6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.
- 7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.
- 7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.
- 7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.
- 7.5 Data storage requirements for each organization shall be provided.
- 7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The

contents of this document can be referenced to a NRMRL or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.